(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 688 580 A1**

(12) EUROPEAN PATENT APPLICATION

(21) Application number: **94109858.4**

(22) Date of filing: **24.06.94**

(51) Int. Cl.[6]: **A61N 5/10**, A61M 29/02

(43) Date of publication of application:
27.12.95 Bulletin 95/52

(84) Designated Contracting States:
AT BE CH DE DK ES FR GB GR IE IT LI LU MC NL PT SE

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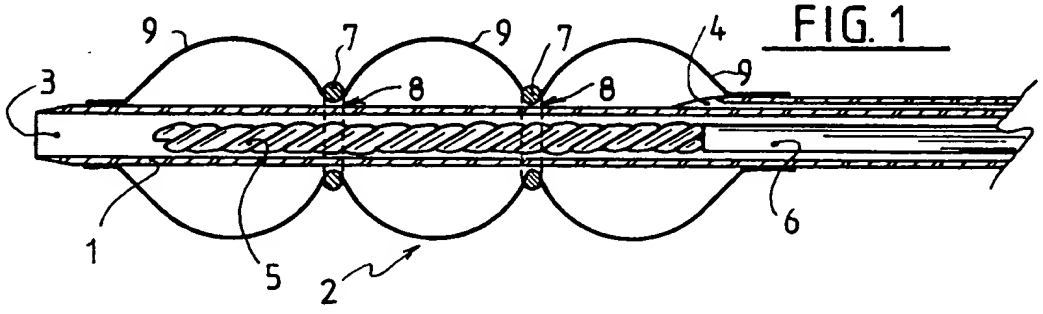
(54) Medical appliance for the treatment of a portion of body vessel by ionising radiation

(57) A balloon catheter comprises a catheter tube 1 surrounded distally by an elongated inflatable balloon 2. Throughout the catheter tube 1 is a longitudinal lumen 3 for positioning a radioactive radiation emitter 5 within the balloon. The catheter comprises a second lumen 4 for directing inflation fluid into the balloon 2. Belt means 7 creating a waist are mounted on the balloon 2 to squeeze it down to nearly the diameter of the catheter 1 thereby leaving a small passge 8 for the inflation fluid. The belt means 7 divide the balloon into sections to assure a close center fit of the catheter 1 within the balloon.

FIG. 1



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This invention relates to a medical appliance for the treatment of a portion of body vessel by ionizing radiation, comprising a catheter, an inflatable elongated balloon distally surrounding the catheter, and lumen means longitudinally extending through the catheter for positioning a radioactive radiation emitter within the balloon.

US Patent N° 5,213,561 describes a device for preventing restenosis after angioplasty comprising, among various embodiments, a catheter having a balloon at its distal end and a center core or tube in which a conventional guidewire is receivable. Particles or crystals of radioactive material are embedded in or mounted on the tube inside the balloon and a retractable shielding sleeve is slidable along the tube to cover the radioactive source, blocking exposure to radiation until it is shifted away. Such a structure is said to allow radiation of a vascular structure immediately following completion of angioplasty, without separately inserting a radiation source.

Standard dilatation balloons are not well suited to transport and to take up radioactive radiating sources because the center core or guidewire lumen tends to warp on the stretch inside the balloon, thereby forming an undulated line. The radioactive radiation source, however, has to be centered as exactly as possible inside the vessel in order to avoid the vessel wall being burned.

The document DE-9102312.2 describes balloon catheters for performing angioplasty procedures followed by radioactive irradiation to prevent restenosis. In a first embodiment, there is provided a catheter closed at its distal end and bearing a dilatation balloon which can be inflated by a fluid medium supplied via a lumen extending longitudinally of the catheter; a radioactive seed affixed to the end of a guidewire may be inserted into the catheter lumen to be brought into the site of angioplasty while the balloon is inflated; according to a variant, the lumen of the catheter may be separated in two parallel channels by a longitudinally extending intermediate wall, one of the channels being for insertion of the fluid for inflating the balloon and the other for insertion of a guidewire having the radioactive seed affixed at its end. In a second embodiment, the catheter comprises an additional channel centered in the catheter lumen by means of two longitudinally extending intermediate walls; the catheter lumen is thus divided into three channels, of which the central channel is for insertion of a radioactive pin affixed at the end of a guidewire and the lateral channels for balloon inflation and for supplying drugs into the blood vessel, respectively. In a third embodiment, the catheter bears two balloons at a distance from one another and which can be inflated separately; the catheter also comprises a central channel centered in the catheter lumen by means of four longitudinally extending walls defining four channels surrounding the central channel; two of the surrounding channels are respectively opening into the balloons for inflation thereof, and the two other surrounding channels are respectively opening between the two balloons to allow injection of drugs in the vessel area comprised between the two balloons; the document indicates that a radioactive seed affixed to the distal end of a guidewire may be placed in the lowest of the surrounding channels; the document also indicates that the radioactive source may be placed in the central channel, further outlining that, as with the second embodiment, the radioactive source may even be driven out of the catheter to directly irradiate the vessel. Apart from the fact that this document does not consider any particular centering of the radioactive source in the body vessel, its various configurations do not allow such a centering.

In the first embodiment of this document DE-9102312.2 no measures are described which would ensure circumferentially uniform radiation impact on the vessel wall and the radial position of the irradiation source is merely determined by gravity, whereby warping of the catheter lumen upon inflation of the balloon will add to the unevenness of radiation distribution in the vessel. In the second embodiment, any warping upon inflation of the balloon will be fully uncontrollable because of the different reactions of the main channel, additional channel and longitudinal walls of the catheter to the stresses resulting from the stretch inside the balloon; this of course makes it impossible to know where and how the radioactive radiation will be distributed in the vesel. In the third embodiment, the situation shows the same drawbacks as for the second embodiment, with some more uncertainty resulting from the additionnal channels.

The document DE-3620123-A1 discloses an apparatus for measuring and irradiating body cavities which permits the placing and positioning of a light conductor at the center of a cavity in order to achieve homogeneous lighting thereof via a dispersing agent. To this effect, a light conductor is located in a tubular catheter surrounded by two optically transparent centering flexible balloons at a distance from each other and which are inflated by a dispersing agent in order to have them rest against the wall of the body cavity. The portion of the catheter which is located between the balloons is stiffer than the rest of the catheter to avoid modification of the distance between the two balloons, for instance due to curving of the catheter. The system is said to be usable for a blood vessel, and the two balloons are occlusion balloons. Occlusion balloons have to be resilient to safely fullfill their task in a vessel of unknown exact shape and

size. Because of this resiliency, occlusion balloons can not be used simultaneously as dilatation balloons. Resilient balloons would overstretch the vessel wall when used with the higher pressures that are required for a successful angioplasty. Of course the doctor has control over the inflation pressure with resilient balloons same as with dilatation balloons, but this is not sufficient for safe angioplasty. With a resilient balloon the doctor has no control over the inflated diameter or over the shape to which the balloon is inflated. Of course, with this apparatus the source could be centered if the balloons are close together, but the additional weldings of two balloons close together make the catheter more complicated and expensive. Furthermore, the added weldings reduce the flexibility of the catheter which is necessary to manoeuvre it through tortuous vessels and to use it in tortuous vessels.

The purpose of this invention is to improve the conditions of radioactive radiation treatment of body vessels by proposing a medical appliance with inflatable balloon for a vessel wall radiation which is uniform around the vessel, an appliance that is highly versatile, simple to manufacture and easy to use.

To this effect, the invention complies with the definitions given in the claims.

In that way, the waist centers the lumen containing the radioactive radiation emitter inside the body vessel at least at the location thereof and substantially eliminates any undulated shape which may be taken by the catheter or lumen containing the radioactive radiation emitter. The stretch occuring upon inflation of the balloon therefore does not affect the positioning of the radioactive radiation emitter within the body vessel. And the appliance may retain a good flexibility allowing its manoeuvre and use in tortuous and/or narrow vessels.

Specifically, it becomes possible to improve dosage control of the radioactive radiation with regard to the distance between radioactive source and vessel wall, whereby overdosage because of too narrow distance and underdosage because of too wide distance to the vessel wall is avoided, and the impact of radiation on the vessel wall is essentially uniform.

The waist may be created by belt means which may be regularly or irregularly spaced from one another over the length of the balloon in order to match any structural configuration and warping tendency of the catheter and balloon assembly.

For inexpensive fitting of existing balloon catheters, the belt means may be made of surgical thread, possibly surgical thread tied with a knot.

To modulate the centering of the catheter within the balloon, the belt means may be made of moulded rings, the length and thickness of which will be chosen as a function of the strength needed to counteract the warping tendency of the catheter.

For safety purposes, the lumen means may have a narrowed distal end whereby the catheter may be normally guided along a guidewire while the radioactive radiation means may be sufficiently thick for not passing through the narrowed distal end. Similarly the lumen means may be closed distally.

The waist or belted balloon catheter may be adapted to several practical configurations, for example to allow use of the technology known under the trade mark MONORAIL. In this case, the lumen means may be closed distally, and the catheter may further comprise a guidewire lumen with an entry and an exit distal of the balloon, which advantageously results in a two lumen catheter construction which will be easily centered within the balloon by the belt means. The catheter may also comprise a guidewire lumen with an entry distal of the balloon and an exit proximal of the balloon, the three lumen catheter so achieved being also correctly centered within the balloon by the belt means.

These and other objects will become readily apparent from the following detailed description with reference to the accompanying drawings which show diagrammatically and by way of example only four embodiments of the invention.

Figures 1 to 4 are respectively longitudinal cuts of the first, second, third and fourth embodiments.

In all the embodiments shown only the portions of the medical appliance which have to be located at the site of treatment have been depicted, the other portions of the embodiments being devised as currently practised in the art. The portion of the body vessel where treatment occurs has not been shown.

The described materials are specifically directed to percutaneous transluminal angioplasty. This is however not limitative and the invention is also applicable to materials directed to the treatment of other body vessels.

The first embodiment of Figure 1 is a balloon catheter comprising a catheter tube 1 surrounded distally by an elongated inflatable balloon 2. The balloon 2 is proximally and distally affixed, for instance welded, to the catheter tube 1 as commonly practised in the art. Throughout the catheter tube 1 is a longitudinal lumen 3 which is adapted to position a guidewire and/or a radioactive radiation emitter within the balloon 2. The catheter 1 comprises a second lumen 4 for directing inflation fluid into the balloon 2. The balloon 2 is shown in inflated condition at the location of a stenosis (not shown) of a blood vessel such as a coronary artery. A radioactive radiation emitter 5, in this example in the form of a coiled filament, is affixed to the

distal end of a guidewire 6, and this coiled filament is sized for a substantial sliding fit within the lumen 3 of catheter tube 1.

Two belt means 7 creating a waist, in this example moulded rings regularly spaced from one another over the length of the balloon, are mounted on the balloon 2 for essentially centering the catheter 1 within the balloon 2. The belt means 3 are affixed to the balloon 2, for example adhesively adhered thereto, and they squeeze the balloon 2 down to nearly the diameter of the catheter thereby leaving a small passage 8 for the inflation fluid supplied to the balloon 2 via lumen 4. The belt means 7 divide the balloon 2 into sections 9 which are substantially similar and they assure a close center fit of the catheter 1 within the balloon 2 at least at the respective locations of the lace, thereby eliminating, or at least strongly minimising, the effects of catheter warping upon inflation of the balloon. The lumen 3 and radioactive radiation emitter 5 in sliding fit therein are thus essentially centered inside the vessel, at least at the locations of the lace.

The second embodiment of Figure 2 is also a balloon catheter comprising a catheter tube 11 distally surrounded by an elongated inflatable balloon 12 affixed to the catheter as usual in the art. Throughout the catheter tube 11 is a longitudinal lumen 13 adapted to position a guidewire and/or a radioactive radiation emitter within the balloon 12. At the distal end of the catheter 11, the lumen 13 has a narrowed distal end 20 the purpose of which is to allow passage of a guidewire while preventing passage of a radioactive radiation emitter which is made a little thicker than the guidewire. The catheter comprises a second lumen 14 for supplying inflation fluid to the balloon 12. A radioactive emitter 15, also in the form of a coiled filament, is affixed to the distal end of a guidewire 16, this coiled filament being sized for a substantial sliding fit within the lumen 13 of catheter tube 11.

As for the embodiment of Figure 1, two belt means 17 creating a waist are formed of moulded rings which are regularly spaced from one another over the length of the balloon and which are mounted on the balloon and adhesively adhered thereto for essentially centering the catheter 11 within the balloon 12. These belt means 17 squeeze the balloon 12 down to nearly the diameter of the catheter in order to leave a small passage 18 for the inflation fluid supplied to the balloon via lumen 14. The belt means 17 also divide the balloon 12 into sections 19 which are substantially similar, and they assure a close center fit of the catheter 11 within the balloon 12 at least at the respective locations of the lace to substantially eliminate the effects of catheter warping upon inflation of the balloon, whereby the lumen 13 and radioactive radiation emitter 15 in sliding fit therein will be essentially centered inside the vessel, at least at the locations of lace.

The third embodiment of Figure 3 is a balloon catheter which makes use of the MONORAIL (trade mark) catheter technology. This balloon catheter comprises a catheter tube 31 distally surrounded by an elongated balloon 32 affixed to the catheter tube. Within the catheter tube 31 is a longitudinal lumen 33 preferably distally closed at a location 40 substantially corresponding to the distal end of balloon 32, which lumen 33 is for allowing passage of a guiding wire 36 provided with a distal radioactive radiation emitter 35 the travel of which is limited for safety purposes by the closed distal end 40 of lumen 33. The catheter also comprises a lumen 34 for supplying inflation fluid to the balloon 32. The catheter 31 further comprises a guidewire lumen 41 with an entry 42 and exit 43 distal of the balloon 32 for accomodating a guidewire 44 in the MONORAIL (trade mark) configuration.

As for the previous embodiments, a waist is created by two belt means 37 which are formed of moulded rings regularly spaced from one another over the length of the balloon 32 and which are mounted on the balloon and adhesively secured thereto for essentially centering the catheter 31 within the balloon 32. Belt means 37 squeeze the balloon 32 to nearly the diameter of the catheter 31 and thereby leave a small passage 38 for the inflation fluid ejected by lumen 34. Belt means 37 divide the balloon 32 into similar sections 39 and they assure a close center fit of catheter 31 within the balloon 32, at least at the respective locations of the lace. As in the previous embodiments, this structure substantially eliminates the effects of catheter warping upon inflation of the balloon and therefore the lumen 33 and radioactive radiation emitter 35 in sliding fit therein will be essentially centered in the body vessel, at least at the locations of lace.

The fourth embodiment of Figure 4 also makes use of the MONORAIL (trade mark) technology. This balloon catheter comprises a catheter tube 51 distally surrounded by an elongated balloon 52. Within catheter tube 51 is a longitudinal lumen 53 for allowing passage of a guiding wire 56 provided with a distal radioactive radiation emitter in the form of a filament 55 sized for a sliding fit into lumen 53. The catheter also comprises a lumen 54 for supplying inflation fluid to the balloon 53 and a guidewire lumen 60, preferably symetrical to lumen 54 with respect to the longitudinal axis of the catheter, having an entry 61 distal of the balloon 52 and an exit 62 proximal of the balloon 52 for accomodating a guidewire 63 in the MONORAIL (trade mark) configuration.

This embodiment also comprises a waist made of two belt means 57 formed of moulded rings regularly spaced from one another over the length of the balloon 52 and adhesively secured on the balloon for essentially centering the catheter 51 within the balloon 52. Belt means 57 squeeze the balloon 52 to nearly the diameter of catheter 51 thereby leaving a small passage 58 for the inflation fluid arising from lumen 54. Belt means 57 divide the balloon 52 in three similar sections 59, thereby assuring a close center fit of catheter 51 within the balloon at least at the respective site of the lace,a structure which substantially eliminates the effects of catheter warping upon inflation of the balloon, despite the three lumen construction. The lumen 53 and radioactive radiation filament 55 in sliding fit therein will therefore be essentially centered in the body vesel, at least at the locations of lace.

Variants may be envisaged.

For instance, the belt means may be made of surgical thread; they may be made possibly of surgical thread tied with a knot.

The belt means may also be made of moulded rings of different length and/or thickness.

The belt means may be irregularly spaced from one another over the length of the balloon. Within this frame, it is possible to have a repartition of belt means providing a central section of the balloon which is longer than a proximal and a distal section thereof.

It is possible to have more than two belt means to constitute the waist in case of long balloon configurations as well as it is possible to have only one belt means forming a waist in case of relatively short balloon configurations.

The belt means may be simply squeezing the balloon, without being affixed thereto. They may also be affixed to the balloon by welding.

And of course, the radioactive radiation emitter may be of any shape, configuration or material, other than the coil or filament described.

Claims

1. A medical appliance for the treatment of a portion of body vessel by ionizing radiation comprising a catheter (1, 11, 31, 51), an inflatable elongated balloon (2, 12, 32, 52) distally surrounding the catheter, and lumen means (3, 23, 33, 53) longitudinally extending through the catheter for positioning a radioactive radiation emitter (5, 15, 35, 55) within the balloon, characterized by a waist (7, 17, 37, 57) on said balloon (2, 12, 32, 52) for essentially centering the catheter (1, 11, 31, 51) within the balloon.

2. A medical appliance according to claim 1, wherein belt means (7, 17, 37, 57) create the waist.

3. A medical appliance according to claim 2, wherein the belt means (7, 17, 37, 57) are regularly spaced from one another over the length of the balloon (2, 12, 32, 52).

4. A medical appliance according to claim 2, wherein the belt means are irregularly spaced from one another over the length of the balloon.

5. A medical appliance according to any preceding claim, wherein the belt means are made of surgical thread.

6. A medical appliance according to claim 5, wherein the belt means are made of surgical thread tied with a knot.

7. A medical appliance according to any of claims 1 to 4, wherein the belt means (7, 17, 37, 57) are made of moulded rings.

8. A medical appliance according to any preceding claim, wherein the belt means (7, 17, 37, 57) are affixed to the balloon (2, 12, 32, 52).

9. A medical appliance according to claim 8, wherein the belt means (7, 17, 37, 57) are adhesively adhered to the balloon (2, 12, 32, 52).

10. A medical appliance according to any preceding claim, wherein said lumen means (13) have a narrowed distal end (20).

11. A medical appliance according to any of claims 1 to 9, wherein said lumen means (33) are closed distally (40).

12. A medical appliance according to any of claims 1 to 9 and 11, wherein said catheter (31) further comprises a guidewire lumen (41) with an entry (42) and an exit (43) distal of the balloon (32).

13. A medical appliance according to any of claims 1 to 9, wherein said catheter (51) further comprises a guidewire lumen (60) with an entry (61) distal of the balloon (52) and an exit (62) proximal of the balloon (52).

FIG. 1

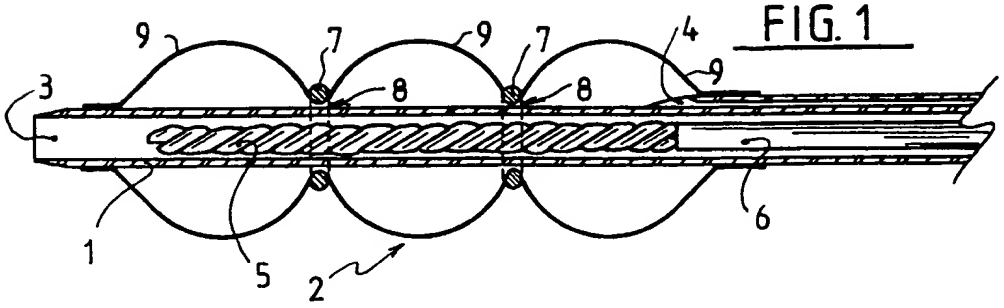


FIG. 2

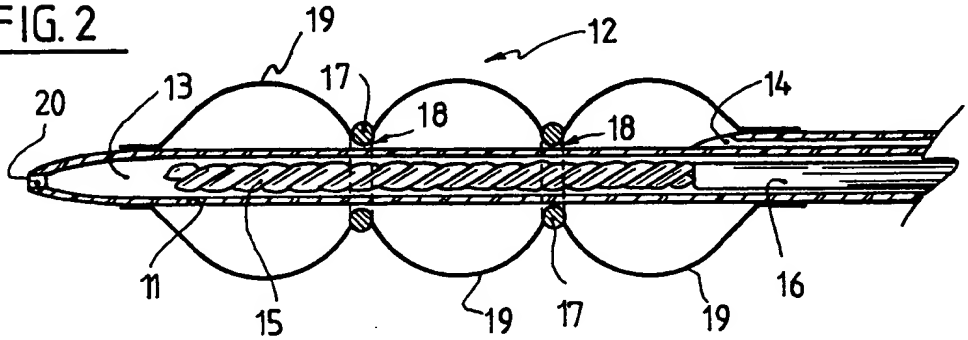


FIG. 3

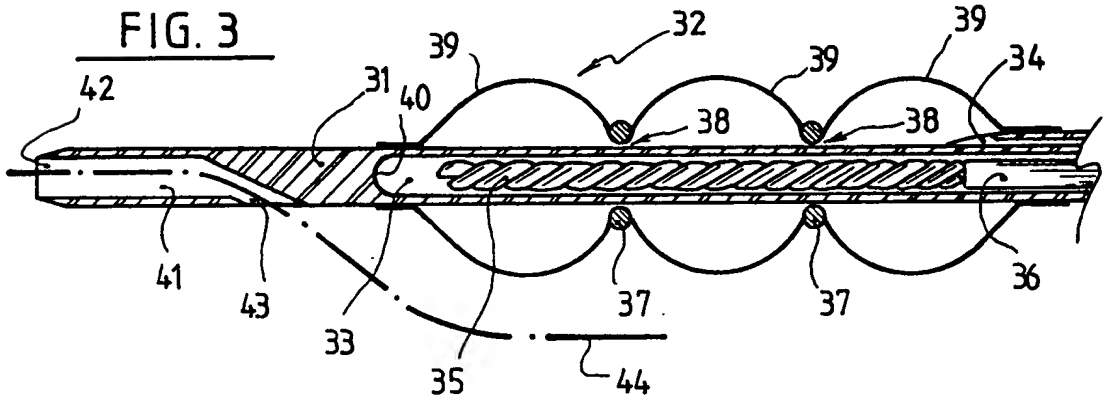
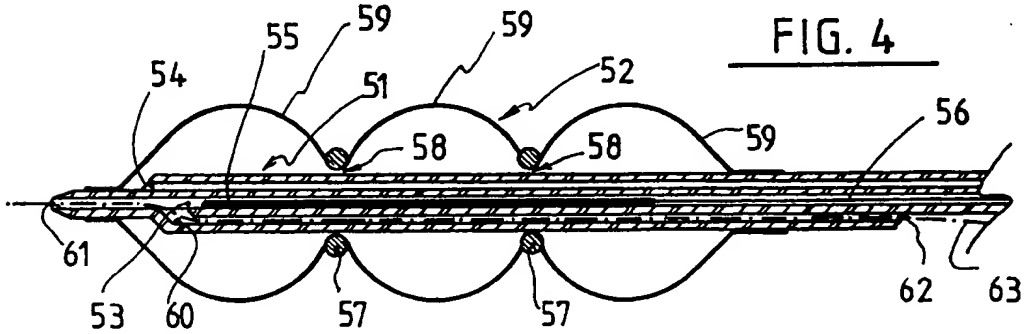


FIG. 4



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EUROPEAN SEARCH REPORT

Application Number
EP 94 10 9858

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
Y,D	DE-U-91 02 312 (A. WEIKL ET AL.) * page 7, line 21 - page 8, line 32; figures *	1,11	A61N5/10 A61M29/02
Y	EP-A-0 409 436 (BAXTER INTERNATIONAL INC.) * column 5, line 33 - column 6, line 12; figures *	1,11	
A	US-A-4 983 167 (H. SAHOTA) * the whole document *	1,3,4, 11,13	
A	EP-A-0 080 436 (SCHNEIDER MEDINTAG AG) * page 11, line 16 - page 13, line 13; figures *	1,10	

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A61N
A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	2 December 1994	Ferrigno, A

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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